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Is the European Laboratory Over-Reach-ing - The Experimentation, Reaction and Product Yielded by the European Union's Registration, Evaluation, and Authorization of Chemicals

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IS THE EUROPEAN LABORATORY OVER-*REACH*-ING? THE EXPERIMENTATION, REACTION AND PRODUCT YIELDED BY THE EUROPEAN UNION'S REGISTRATION, EVALUATION, AND AUTHORIZATION OF CHEMICALS

I. BEFORE THE REACTION: AN INTRODUCTION TO REACH

On July 10, 1976, in Seveso, Italy, just north of Milan, a mushroom cloud formed above a small chemical manufacturing plant, unleashing thirty to forty kilograms of TCDD into the atmosphere.[1] TCDD is the most dangerous form of dioxin and a major component found in Agent Orange; it has an extremely adverse effect on the ecosystem and can cause numerous human diseases.[2] Due to the dioxin spill, the human population suffered severe dermatologic and hepatic repercussions which caused potentially lethal conditions, while various wild and domestic animals were either instantly and fatally poisoned by the chemical or slaughtered later as a preventive measure.[3] Further consequences of the spill still remain unknown and undetermined.[4] The European Union, attempting to control and enforce industrial safety in the wake of the leak at Seveso, conducted an assortment of experiments by issuing a series of directives over the next decade, some of which became known as the Seveso Directives.[5]

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1. *See* Mitsuo Kobayashi & Masamitsu Tamura, *Explosion of Chemical Plant in Seveso, Italy*, July 10, 1976, http://shippai.jst.go.jp/en/Detail?fn=2&id=1300002 (describing Seveso disaster). TCDD is a common form of dioxin; the spill caused *2,3,7,8-tetrachlorodibenzo-p-dioxin* to be released into the atmosphere surrounding the chemical plant. *Id.* at 1-2.

2. *See* Lesa Aylward et al., *Twenty-five Years of Dioxin Cancer Risk Assessment*, 19 NAT. RES. & ENV'T. 31, 32 (2005) (discussing use of Agent Orange during Vietnam Conflict and impact of dioxins generally on humans and environment in Vietnam and during leak at Seveso).

3. *See id.* at 31 (discussing impact of dioxin poisoning on humans and environment). The main form of dermatologic harm suffered by the victim is chloracne. *Id.* Chloracne is an acne-like condition found on the face, neck and back among people exposed to TCDD. *Id.* TCDD has been known to cause chloracne and death due to liver damage in rabbits. *Id.*

4. *See* E. Homberger et al., Abstract, *The Seveso Case Accident: Its Nature, Extent and Consequences*, 22 ANNALS OCCUP. HYG. 327 (1979), *available at* http://annhyg.oxfordjournals.org/cgi/content/abstract/22/4/327 (discussing environmental, ecological, and human health consequences of spill at Seveso).

5. *See* K.J. de Graaf & J.H. Jans, *Colloquium Article: Liability of Public Authorities in Cases of Non-Enforcement of Environmental Standards*, 24 PACE ENVTL. L. REV. 377, 382 (2007) (describing development of Seveso Directives).

These directives eventually led to calls for reform and alternative legislation, resulting in the subsequent development of the system of Registration, Evaluation and Authorization of Chemicals (REACH), a regulation that dictates which chemicals are manufactured and sold throughout the European Union.[6] REACH shifts the burden of assessing whether a particular chemical will or will not violate the regulation onto chemical manufacturers and importers.[7] Absent specific exemptions, companies throughout the globe, including American companies, will need to comply with REACH if they wish to continue using or selling chemicals within Europe.[8] Though still in its infancy, REACH's first substantive provision, preregistration, commenced on June 1, 2008.[9] Chemicals that have priority and must be preregistered are those included on a list of "Substances of Very High Concern" (SVHCs).[10] The registration of all chemicals under REACH's jurisdiction will be phased-in over the course of eleven years.[11]

6. *See* Council Regulation 1907/2006, art. 6, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), 2006 O.J. (L 396) 1, 62 (EC) (establishing European chemicals regulation and agency); *see also* Daniel Tanuro, *Toxic Chemical Defense Sabotaged*, INT'L VIEWPOINT (July–Aug. 2005), http://www.internationalviewpoint.org/spip.php?article854 (describing REACH's development).

7. *See* Treaty Establishing the European Community, art. 249, Nov. 10, 1997, 1997 O.J. (C 340) 3 (defining directives and establishing power by European Parliament to make directives). Directives are not self-executing; they are binding, and it is up to individual Member States to choose form and method of executing directives. *Id.* For a further discussion of European regulations in general, and REACH in particular, see *infra* notes 23-93 and accompanying text; *see also* Julie A. Hatcher, *REACH Candidate List of Priority Substances of Very High Concern (SVHC) Now Available for Comment*, CLIENT ALERT No. 730, July 24, 2008, at 3-7, *available at* http://www.eli.org/pdf/alerts/Latham_Watkins_07-24-08.pdf (describing purpose of REACH).

8. Kenneth Rivlin et al., *The REACH of Europe's Regulatory System*, N.Y. L.J., July 14, 2008, at 9, *available at* http://www.law.com/jsp/nylj/PubArticleNY.jsp?id=1202422925275 (describing background of effect of REACH on companies).

9. *See* Council Regulation 1907/2006, art. 76(1)(g), 138(5), REACH, 2006 O.J. (L 396) 173, 230 (EC) (defining pre-registration period and duties for manufacturers); *see also* Hatcher, *supra* note 7, at 1-2 (detailing preregistration process). Preregistration, during which companies could preregister chemical data with the ECHA, took place between June 1, 2008, and December 1, 2008. *Id.* Certain chemicals have priority over others, because chemicals that are on the SVHC list will trigger more REACH requirements and have "potentially value-chain implications." *Id.* The chemicals on the SVHC list are deemed the most dangerous to the environment and human health, and must be the first chemicals scrutinized under the new regulation. *Id.* For a further discussion of chemicals on the SVHC list and the list's impact, see *infra* notes 61-72 and accompanying text.

10. *See* Hatcher, *supra* note 7, at 1-2 (describing pre-registration of SVHCs).

11. *See* Marla Cone, *European Parliament OKs World's Toughest Law on Toxic Chemicals*, S.F. CHRON., Dec. 14, 2006, at A12, *available at* http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2006/12/14/MNGR2MV8UT1.DTL&hw=toxic+chemicals&sn=001&sc=1000/ (describing duration of implementation of REACH).

The effects of the REACH experiment, needless to say, are and will continue to be profound, as companies are forced to replace chemicals that are hazardous to the environment and human health with safer alternatives.[12] The United States, presently the world's leader in chemical production, has fought vigorously against the implementation of such a regulation.[13] Although the chemical industry in the United States has been subjected to the Toxic Substances Control Act of 1976 (TSCA) for more than three decades, REACH's provisions go beyond what has previously been asked of the chemical industry domestically.[14] While the American chemical industry must comply with the regulation, the cost of compliance during the registration period will be substantial to companies in both the United States and Europe.[15] Both private and government agencies are assisting with the industry's compliance by providing notices concerning timetables, restricted chemicals, and other preregistration information for those companies and manufacturers that are late registrants.[16]

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12. *See id.* (describing REACH's intention).

13. *See id.* (detailing United States' stance against REACH); *see also* Mamta Patel, *ChemCon Asia 2009 Preview: REACH and GHS in a Global Context*, CHEMICAL WATCH, Jan. 15, 2009, *http://chemicalwatch.com/1619* (noting China expected to surpass United States as world's leading chemical producing country by 2015).

14. *See generally* The Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601-2629 (2006) (outlining provisions of TSCA); *see also* Cone, *supra* note 11, at A12 (describing TSCA's lack of authority); *but see* Daniel A. Farber, *Five Regulatory Lessons from REACH* 23 (Nov. 13, 2008) (unpublished manuscript, University of California, Berkley, Public Law Research Paper No. 1301306), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1301306# (detailing need to attack "tyranny of the status quo"). REACH, unlike the TSCA, does not "grandfather in" chemicals; in other words, REACH does not remove those chemicals from the testing or registration process because they came onto the market before a certain arbitrary date. *Id.*

15. *See* Cone, *supra* note 11, at A12 (describing the economic impact of compliance). The cost to European industry has been estimated to be between $2BB and $6BB over the eleven-year phase-in period. *Id.* Companies and manufacturers, meanwhile, scrambled to set up committees, management programs and the like, to preregister chemicals before the December 1, 2008 deadline. *See also NAM Update on EU REACH Chemicals Management Program*, NAT'L ASS'N OF MANUFACTURERS (2009), http://www.nam.org/PolicyIssueInformation/InternationalEconomicAffairsPolicy/EUREACHChemicalsManagementProgram.aspx (describing preregistration procedures of companies). For a further discussion of how companies are managing, see *infra* notes 124-31, 176-97 and accompanying text.

16. *See NAM Update on EU REACH Chemicals Management Program*, NAT'L ASS'N OF MANUFACTURERS (2009), http://www.nam.org/PolicyIssueInformation/InternationalEconomicAffairsPolicy/EUREACHChemicalsManagementProgram.aspx (describing necessity of preregistration). The National Association of Manufacturers is working with the United States government to help companies with REACH registration, especially those companies who have missed the preregistration deadline, or encountered difficulties with European agents. *Id.*

This Comment enters the laboratory and explores the elements of the experiment that is REACH; what the regulation is designed to cover, its purpose, its effect, and its future environmental and economic impact on Europe, the United States, and the international community. Part II ventures further into the laboratory to discuss the background of REACH and its purpose.[17] Part III analyzes the experiment: (1) the regulation itself, (2) what REACH accomplishes, and (3) what industries it affects, both environmentally and economically.[18] Part IV discusses REACH's future impact on other laboratories in the international community, American laboratories in particular, and how the European chemical regulation experiment may influence them.[19] Finally, Part V prepares for further experimentation and determines that Europe is not overreaching in its experiment to regulate the chemical industry; instead, although the effect of REACH will take years or decades to be fully realized, Europe is levying minimal costs on numerous industries while protecting the environment.[20]

II. GETTING TO THE LABORATORY: THE PREPARATION FOR AND IMPLEMENTATION OF REACH

Since the 1970s, several decades of ever-increasing production of dangerous and deadly chemicals in Europe have caused an ever-increasing amount of environmental and human-health harm.[21] In the wake of chemical disasters such as Seveso, a wave of health and environmental consciousness encouraged Europe to enter the laboratory and implement a more stringent and comprehensive chemical regulation.[22] Europe's declared purpose was to protect the

17. For a discussion of the development and implementation of REACH, see *infra* notes 21–92 and accompanying text.

18. For a discussion of the EU's legislation regulating, evaluating and authorizing the use of chemicals, see *infra* notes 93–114 and accompanying text.

19. For a discussion of how the international community will be affected by REACH, see *infra* notes 115–98 and accompanying text.

20. For a discussion of how REACH is already affecting the international community, and how its effect will only strengthen in the future, see *infra* notes 199–214 and accompanying text.

21. *See* Tanuro, *supra* note 6 (discussing rise of atmospheric chemical poisoning and impact on environment and human health). Doctors and biologists have become increasingly worried over three particular categories of manufactured toxic chemicals, PBDEs, PCBs and OCPs, and their well-known effects on the ecosystem and less well-known effects on human health. *Id.*

22. *See* Lyndsey Layton, *Chemical Law Has Global Impact: E.U.'s New Rules Forcing Changes by U.S. Firms*, WASH. POST, June 12, 2008, at A1, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2008/06/11/AR2008061103569_pf.html (discussing Europe's chemical regulations as result of rise in consciousness towards protecting consumers, environment and human health).

planet and halt the growing perception in the international community that the United States has allowed the chemical industry a "free ride" when it comes to regulation.[23] In December 2006, the European Union voted in favor of a proposed system to regulate the chemicals found on the European market.[24] Centralizing a previously scattered body of legislation and inverting the burden of proof onto the chemical manufacturer to show that a particular substance is safe, REACH represents an important change in Europe's regulatory scheme.[25] REACH also distinguishes among the different roles chemicals play in the industry, and regulates accordingly.[26]

A. Preparing the Experiment: REACH's Purpose

REACH's ultimate goal is to "ensure a high level of protection of human health and the environment."[27] The European Parliament specifically rejected the United States' model of chemical regulation by adopting the precautionary principle; REACH, in effect, preempts complete scientific proof of the harm of a chemical by placing the burden of proving a chemical's safety on the industry.[28]

23. *See id.* (discussing European perception of United States' attitude toward chemical industry). Professor Sheila Jasanoff of Harvard University's John F. Kennedy School of Government notes that Europe and the international community believe that "being a good global citizen in the era of sustainability" means having concern for the environment. *Id.*

24. *See* Donald Stever, *Law of Chemical Regulation and Hazardous Waste*, 1 L. OF CHEM. REG. & HAZARDOUS WASTE § 2:78 (2008) (setting background of REACH's passing by European lawmakers).

25. *See id.* (describing purpose of REACH).

26. *See generally* Peter Bogaert et al., *REACH and its Impact on Cosmetics*, Covington and Burling, LLP (Oct. 2008) (distinguishing between substances and articles).

27. Council Regulation 1907/2006, art. 1, REACH, 2006 O.J. (L 396) 47 (EC) (announcing purpose of REACH); *see also* Diana Bowman & Geert van Calster, *Reflecting on REACH: Global Implications of the European Union's Chemical Regulation*, 4 NANOTECH. L. & BUS. 375, 377 (2007) (discussing purpose and enactment of REACH); *see also REACH: Europe's Chemical Regulation Takes Off?*, ACRONYM REQUIRED, Sept. 18, 2007, http://acronymrequired.com/2007/09/reach-europes-chemical-regulation.html (discussing purpose of REACH). The purpose of REACH is "to make up for lax regulation in the chemical industry that has led to unprecedented *levels* of toxic chemicals in the environment and exposures in wildlife and humans." Acronym Required, http://acronymrequired.com/2007/09/reach-europes-chemical-regulation.html (Sept. 18, 2007, 19:18 EST) (discussing purpose of REACH).

28. *See* Council Regulation 1907/2006, art. 1.3, REACH, 2006 O.J. (L 396) 47 (EC) (defining principle upon which REACH is based). The European Parliament specifically notes that the Regulation's "provisions are underpinned by the precautionary principle" and apply the principle's burden onto the manufacturers. *Id.* Under REACH, "[i]f a chemical *might* be a problem, it is not authorized until data exists which can exonerate it." *See* Jody A. Roberts, *Collision Course? Science,*

Perhaps even more importantly, during the current global economic downturn, REACH strives to save billions of dollars in future health costs and to compel companies to manufacture "greener" chemicals by implementing a market incentive with which to comply.[29] This stems from the concern that "exposure to toxic substances in food, water, air, and from everyday products, may play an important role in chronic disease in humans and wildlife."[30]

B. REACH: Yield of the European Laboratory's Chemical Reaction

REACH is a "comprehensive framework for analyzing the impact chemicals may have on health and the environment" throughout Europe.[31] It sets forth: rules for the registration of chemicals and the evaluation of their data, risks and safety; restrictions on certain banned categories; and procedures for the authorization of allowable chemicals.[32] The European Parliament delegated the duty to enforce this process to the newly created European Chemicals Agency (ECHA).[33] The legislation further divides chemicals into

Law, and Regulation in the Emerging Science of Low Dose Toxicity, 20 VILL. ENVTL. L.J. 1, 13 (2009) (describing precautionary principle); *see also* Bowman & van Calster, *supra* note 27, at 382 (concluding REACH's purpose will be met).

29. *See* Jeremy Faludi, *What Does REACH Mean for Products?*, WORLD CHANGING, Aug. 3, 2007, http://www.worldchanging.com/archives/007064.html (determining impact of REACH's purpose on environment and human health).

30. LOWELL CENTER FOR SUSTAINABLE PRODUCTION, CHEMICALS POLICIES IN EUROPE SET NEW WORLDWIDE STANDARD (Oct. 10, 2003) (discussing problem of increasing body burdens and impacts of toxic chemicals). Studies are showing that toxic substances play a role in the increasing rates of childhood cancer, asthma, and learning and neurobehavioral disabilities. *Id.*

31. Treaty Establishing the European Community, Nov. 10, 1997, 1997 O.J. (C 340) 3, art. 37, 249 (defining regulation and establishing power by European Parliament to make regulations applicable to all Member States). Regulations differ from directives most importantly in that they are self-executing; it is immediately binding on member states when it passes, versus a directive, which must be passed by the individual member states. *Id.* REACH, a regulation, is therefore uniformly imposed upon all Member States, thereby allowing for comprehensive application throughout Europe. *See also* Charles E. McClure, Jr., *Legislative, Judicial, Soft Law, and Cooperative Approaches to Harmonizing Corporate Income Taxes in the US and the EU*, 14 COLUM. J. EUR. L. 377, 410 (2008) (defining European Union modes of legislation); *see also* Rivlin et al., *supra* note 8 (defining background and basic provisions of REACH).

32. *See* Rivlin et al., *supra* note 8 (describing procedures that REACH puts in place).

33. *See id.* (describing European Parliament's delegation of REACH to ECHA). The ECHA was designed specifically for the purpose of administering REACH and regulating chemical manufacturing in and importation into Europe, and is headquartered in Helsinki, Finland. *See* European Chemicals Agency, http://echa.europa.eu/home_en.asp (last visited Mar. 5, 2009) (describing background and purpose of ECHA). For a further discussion of the ECHA, see *infra* notes 47-51 and accompanying text.

two groups—substances and articles—and manufacturers must determine under which group their product falls to properly comply with REACH.[34]

1. *The Experiment: REACH Defined*

REACH requires any company either manufacturing within or exporting chemicals into the European Union, in excess of one metric ton per year, to preregister with the ECHA.[35] Manufacturers must then register officially, on a sliding scale, beginning after preregistration ends.[36] Those companies whose chemicals were not preregistered by December 1, 2008, must have the chemicals fully registered by November 2010 for those chemicals to even be considered for placement on the European market.[37] Under REACH, the chemical industry bears the burden of ensuring that all chemicals and chemical products placed onto the European market have been properly registered with the ECHA.[38] Over a period of eleven years REACH consequently replaces disjointed rules with one comprehensive European program: all manufacturers registering their chemicals must "submit health and safety data, [while] replac[ing] the most hazardous [chemicals] with safer alternatives."[39]

a. *The procedure: basic provisions*

The regulation requires that the industry—manufacturers and importers of chemicals and chemical products—obtain and main-

34. *See* European Chemicals Agency, *supra* note 33 (discussing substances and products).

35. *See* Council Regulation 1907/2006, art. 28, REACH, 2006 O.J. (L 396) 101 (EC) (describing duty for manufacturers to preregister substances to ECHA). The preregistration period began on June 1, 2008, and concluded on December 1, 2008. *Id.* at 102.

36. *See* ENV'T DIRECTORATE GEN., EUROPEAN COMMISSION, REACH IN BRIEF 5-9 (2007), *available at* http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf (discussing preregistration and registration procedure under REACH). Substances in excess of one thousand tons and very toxic to aquatic organisms greater than one hundred tons must be registered by November 30, 2010. *Id.* at 9. Substances between one hundred and one thousand tons must be registered by May 31, 2013. *Id.* All other substances greater than one ton must be completely registered by May 31, 2018. *Id.*

37. *See* Rivlin et al., *supra* note 8 (discussing preregistration of substances). This includes "existing" substances, which, if preregistered, are allowed a longer registration period, due to their nature and lack of data immediately available. *Id.* For a further discussion of "existing" substances, see *infra* notes 72-80 and accompanying text.

38. *See* Council Regulation 1907/2006, art. 6, REACH, 2006 O.J. (L 396) 62, 63 (EC) (placing obligation on industry to register substances); *see also* Rivlin et al., *supra* note 8 (describing function of registration with ECHA).

39. Cone, *supra* note 11, at A12 (describing REACH legislation).

tain data on its chemicals and manage them safely.[40] To reduce animal testing, data sharing on previously completed tests on the same or similar data was required; this step, termed pre-registration, required manufacturers who wished to register any product with ECHA in the future to have informed the ECHA and file their data by December 1, 2008.[41]

During registration, the ECHA evaluates the data to determine if further testing is necessary and checks the data for compliance with the registration requirements.[42] Only those chemicals or products "with properties of very high concern" (SVHCs) are then subject to authorization by the ECHA, which determines whether the chemicals can be placed onto the market or not; all other chemicals or chemical products, whether "existing" or "new," are allowed on the market.[43] To enable authorization of their chemicals or products of very high concern, applicants must "show that the risks associated with the uses of these [chemicals] are 'adequately controlled,' the socio-economic benefits of their usage outweigh the risks, and there are no suitable alternatives."[44] Applicants, therefore, must analyze and disclose whether there are safer chemical substitutes or technologies available; if there are, applicants must prepare substitution plans, or, if not, applicants should provide information on research and development potential.[45] This system replaces the previous patchwork of forty different Regulations and Directives, amongst them the Seveso Directives, that had regulated the chemical industry in Europe over the past three decades, yielding mostly negative results.[46]

40. *See* ENV'T DIRECTORATE GEN., *supra* note 36, at 5-9 (discussing registration procedure under REACH).

41. *See* Mike Penman & Guido Bognolo, *The EU's REACH Will Have a Profound Impact on Cosmetics and Personal Care Exporters to Europe*, ICIS, Apr. 3, 2008, http://www.icis.com/Articles/2008/04/07/9113501/cosmetics-and-personal-care-companies-need-to-prepare-for-the-eus-reach.html (discussing preregistration procedure and purpose under REACH).

42. *See* ENV'T DIRECTORATE GEN., *supra* note 36, at 11-12 (noting evaluation procedures under REACH).

43. *See* Council Regulation 1907/2006, art. 56, REACH, 2006 O.J. (L 396) 139-41 (EC) (defining authorization); *see also* ENV'T DIRECTORATE GEN., *supra* note 36, at 12-14 (noting authorization procedures and restrictions under REACH).

44. Bradley C. Karkkainen, *Bottlenecks and Baselines: Tackling Information Deficits in Environmental Regulation*, 86 TEX. L. REV. 1409, 1433 (2008) (explaining burden of manufacturer to prove socio-economic benefit of substance outweigh risks); *see also* Penman & Bognolo, *supra* note 41 (noting burden on industry to prove safety and cost-benefit analysis to gain authorization of chemicals of very high concern).

45. *See* Karkkainen, *supra* note 44, at 1433 (noting further applicant burdens).

46. *See* ENV'T DIRECTORATE GEN., *supra* note 36, at 3, 15 (detailing background of REACH). Previously there were different rules concerning what chemicals could be "grandfathered in" or not, for example. *Id.* This system did not produce

b. The scientist: ECHA

The ECHA, like any good scientist, has many responsibilities and functions to control the REACH experiment in the European laboratory. The ECHA

> manages the registration process, carries out dossier evaluations and co-ordinates the substance evaluation process and generally takes decisions resulting from evaluations, except in cases of disagreement . . . [and i]t provides expert opinions to the Commission in the authorization and restriction procedures and has duties with regard to confidentiality and access to information.[47]

Centralizing these responsibilities enables the ECHA to provide consistency and coordination to Europe's registration, evaluation and authorization experiment that was lacking under previous European chemical legislation.[48] These duties enable the ECHA, after consultation with Member States, to both include chemicals and chemical products that pose a risk to the environment or human health on the list for "substance evaluation," and publish a "candidate list" of SVHCs, which are chemicals and products subject to authorization.[49] Possessing the power to add a chemical or product to the list if it believes one poses a risk to human health or the environment, the ECHA must constantly and consistently review the list.[50] The ECHA, furthermore, is responsible for handling "requests for exemption from the registration requirement for product . . . research and development, and facilitates the sharing of animal test data at the pre-registration stage . . . ."[51]

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sufficient information about the chemicals and products existing on the market and their effects on human health and the environment. *Id.* The result was that in the thirteen years before REACH, only 141 high-volume chemicals were even identified for testing and risk assessment. *Id.*

47. *Id.* at 14 (listing ECHA's duties); *see also* European Chemicals Agency, ECHA MISSION, http://echa.europa.eu/about/mission_en.asp (last visited Mar. 12, 2009) (laying foundation of purpose of ECHA).

48. *See* ENV'T DIRECTORATE GEN., *supra* note 36, at 5 (describing function of ECHA); ECHA MISSION, *supra* note 47 (laying foundation of purpose and discussing mission of ECHA).

49. *See* Rivlin et al., *supra* note 8 (discussing ECHA role beyond registration). The process compels applicants attempting to register potentially harmful chemicals to disclose further data of the chemical when they register. *Id.*

50. *See id.* (noting ECHA's ability to add substances to list).

51. ENV'T DIRECTORATE GEN., *supra* note 36, at 14 (describing further functions of ECHA).

2. *The Chemical Reaction: REACH's Umbrella*

The penumbra of the chemical reaction of the REACH experiment encapsulates both "substances" (the chemicals themselves) and "articles" (the final product containing substances).[52] REACH classifies all substances together; while certain substances are classified as substances of very high concern (SVHCs) and are reviewed under heightened scrutiny, REACH has removed from the lab the now defunct definitions of either "new" or "existing" substances.[53] The manufacturers of substances and articles, moreover, are distinguished from those non-registering downstream users.[54]

a. Element #1: Substances

Substances are the chemicals themselves: a chemical element or compound found in either its natural state or after a manufacturing process.[55] There is no definitive list of substances, allowing the term to encapsulate more than just "traditional" chemicals in its gamut.[56] This, in turn, sanctions the ECHA to authorize or reject SVHCs, the highest risk substances in the industry.[57] All chemicals, whether "existing" or "new" under the old patchwork legislation, *must* be preregistered with REACH; where data is lacking on substances previously considered "existing," a longer registration period is available.[58] The result is that substances are now either allowed on the market or restricted based solely on their nature, not on whether they are already regulated substances.[59]

52. *See* Council Regulation 1907/2006, art. 3, REACH, 2006 O.J. (L 396) 53, 54 (EC) (defining "substances" and "articles").

53. *See* Karkkainen, *supra* note 44, at 1432-33 (noting manufacturers must register both new and existing chemicals during phase-in period). There is an exception, where companies registering "existing" chemicals are afforded a longer grace period for registration. *Id.*; *see also* Rivlin et al., *supra* note 8 (describing SVHCs and difference between "new" and "existing" chemicals).

54. *See* Karkkainen, *supra* note 44, at 1432-33 (describing downstream users).

55. *See* Council Regulation 1907/2006, art. 3.1, REACH, 2006 O.J. (L 396) 53 (EC) (defining substances). This includes "any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition." *Id.*

56. *See* Rivlin et al., *supra* note 8 (explaining wide use of term "substances").

57. *See id.* (describing classification of and procedure for substances of very high concern); *see also* ENV'T DIRECTORATE GEN., *supra* note 36, at 12-13 (defining substances of very high concern for authorization process). For a further discussion of SVHCs, see *infra* notes 59-70 and accompanying text.

58. *See* ENV'T DIRECTORATE GEN., *supra* note 36, at 3 (detailing previous European legislative framework).

59. *See id.* (describing elimination of classifications); *see also* Farber, *supra* note 14, at 23 (noting lesson to learn from REACH is to attack status quo of dividing chemicals into "old" or "new" categories).

(i) The catalyst: Substances of very high concern (SVHCs)

On October 28, 2008, the ECHA published a list of the first fifteen SVHCs.[60] The EHCA alone retains the power to authorize or ban these substances.[61] The substances on the SVHC list may be authorized, and subsequently made available on the European market, only if the applicant company can demonstrate both the socio-economic necessity for the substance and the lack of a safer alternative.[62] While certain substances may be exempted from the legislation's ambit, the European Union determined that these SVHCs are substances that pose the greatest threat to the environment and human health.[63]

The substances chosen for the original SVHC list are either: (1) carcinogenic, mutagenic or toxic to reproduction (CMR); (2) persistent, bioaccumulative and toxic (PBT); or (3) very persistent and very bioaccummulative (vPvB).[64] The individual Member States determined that these fifteen substances, the riskiest chemicals to potentially be on the market, were to be given priority when

60. *See* European Chemicals Agency, Candidate List of Substances of Very High Concern for Authorisation, http://echa.europa.eu/chem_data/candidate_list_table_en.asp (last visited on Mar. 11, 2009) (listing substances placed on SVHC list). The list is constantly updated; as of March 11, 2009, the list contains eighteen substances. *Id.* (listing substances currently on SVHC list); *see also* Annelie Struessmann, *REACH Update: Substances of Very High Concern*, COSMETICS & TOILETRIES, Nov. 18, 2008, *available at www.cosmeticsandtoiletries.com/regulatory/reach/34699514.html* (discussing publication of REACH SVHC list).

61. *See* Council Regulation 1907/2006, art. 56, REACH, 2006 O.J. (L 396) 139-41 (EC) (defining authorization and authorization procedure).

62. *See id.*, art. 7, 31.1, 33 (providing information for manufacturers of proper procedure to register substances of very high concern); *see also* EUROPEAN CHEMICALS AGENCY, SHORT SUMMARY: OBLIGATIONS LINKED TO THE CANDIDATE LIST OF SUBSTANCES OF VERY HIGH CONCERN (Nov. 4, 2008), *available at* http://echa.europa.eu/doc/candidate_list/candidate_list_obligations.pdf (detailing obligations of manufacturers to register substances of very high concern); *see also* Rivlin et al., *supra* note 8 (describing process of authorizing SVHCs); *see also* Hatcher, *supra* note 7, at 1, 2 (providing REACH requirements for SVHCs).

63. *See* Press Release, European Chemicals Agency, ECHA Member State Committee Agrees on the Identification of 14 Substances of Very High Concern (Oct. 9, 2008), *available at* http://www.echa.europa.eu/doc/press/pr_08_34_msc_indentification_svhc_20081009.pdf (describing purpose of list of SVHCs).

64. *See* Council Regulation 1907/2006, art. 57, REACH, 2006 O.J. (L 396) 141-42 (EC) (defining substances to be included in Annex XIV). Annex XIV contains the list of Substances Subject to Authorization, thus the list of SVHCs. *Id.* (noting list of substances in Annex XIV may be on SVHC list); *see also* Press Release, European Chemicals Agency, *supra* note 63 (describing inclusion of substances on Candidate List); *see also* Hatcher, *supra* note 7, at 3-7 (listing characteristics of substances on SVHC list); *see generally* Struessmann, *supra* note 60 (identifying chemicals on original SVHC Candidate List and defining Annex XIV).

subjected to the authorization process.[65] Yet these fifteen substances should be considered non-starters; they will probably never be authorized and, consequently, restricted, as the list includes such potent and commonly found substances as lead hydrogen and triethyl arsenate, diarsenic trioxide, sodium dichromate, dehydrate and short chain chlorinated paraffins (SCCPs).[66] Perfluorooctanoic acid (PFOA) is an example of a commonly used substance that is anticipated to eventually be placed on the list.[67]

There are, however, two caveats to the original SVHC list. The first is that on September 17, 2008, nongovernmental organizations (NGOs) compiled and released a parallel list of chemicals—appropriately titled "Substitute It Now" (SIN)—they hope to be prohibited.[68] Chemicals found on the SIN list, in addition to those found on the SVHC list, include triclosan, ethylene oxide and formaldehyde, and could eventually make their way onto the ECHA's legally binding SVHC list.[69] The second caveat is that many substances do

65. *See* Press Release, European Chemicals Agency, *supra* note 63 (describing reason for original Candidate List of SVHCs). The ECHA based their findings on the assessment of the substances' inherent properties, harm from potential exposure and market volume. *Id.* Only those substances on the SVHC list must undergo the authorization process. *Id.*

66. *See* Press Release, *supra* note 63 (listing Candidate List of SVHCs); *see also* Hatcher, *supra* note 7, at 3-7 (listing Candidate List of SVHCs). Lead hydrogen and triethyl arsenate, though once widely used in pesticides and wood preservatives, have been mostly restricted in European manufacturing by EU legislation; the worry is that they are being imported into the EU, however, as they are still used in the production of circuit boards and other electronic equipment. Hatcher, *supra* note 7, at 3-7. Diarsenic trioxide, found in glass, arsenic alloys and semiconductors, may cause cancer, burns, and is very toxic if swallowed, and is very toxic to aquatic organisms and could cause long-term negative effects in the aquatic environment. *Id.* Sodium dichromate, dihydrate, found in the manufacture of metal finishing, oils, perfumes and other compounds, may cause cancer, genetic defects, and serious damage to the skin and one's health from inhalation and long-term exposure, as well as long-term, adverse effects in the aquatic environment. *Id.* SCCPs, found in lubricants, flame retardants in textiles and rubber, and paints, have toxic effects on the environment and environmental growth. *Id.*

67. *See* Layton, note 22, at A1 (discussing possible SVHC chemicals). PFOA is used to make Teflon and other substances used in food packaging, carpet, clothing and electrical equipment. *Id.*

68. *See* David Steinberg et al., Steinberg & Assoc., *Regulatory Review: The Impact of REACH on the United States*, COSMETICS & TOILETRIES, Nov. 26, 2008, *available at* http://www.cosmeticsandtoiletries.com/regulatory/reach/35143314.html (describing SIN list). NGOs involved in compiling the list included the European Environmental Bureau, the World Wildlife Fund European Policy Office, Friends of the Earth Europe, Greenpeace European Unit, Instituto Sindical de Trabajo Ambiente y Salud, The European Consumer's Organization, Women in Europe for a Common Future, The Center for International Environmental Law and the Health and Environment Alliance. *Id.*

69. *See id.* (detailing chemicals found on SIN list). Triclosan is commonly used in the United States in deodorants and over-the-counter drugs, such as antiseptics and toothpaste; it accumulates in sewage treatment plants and causes bac-

not even have to be registered, since they are already banned in the European Union.[70] The ECHA consequently does not have to require registration for or concern itself with evaluating the potential authorization of asbestos, benzene in toys, or lead carbons in paint, as they are already prohibited under REACH.[71]

(ii) "New" vs. "existing" vs. exempt substances

"Existing" substances were formerly those established on the European market between January 1, 1971 and September 18, 1981,[72] while "new" substances were those introduced onto the European market after September 18, 1981.[73] Under those previously faulty European chemical regulation experiments, "existing" substances were any listed in the European Inventory of Existing Commercial Chemical Substances (EINCES), while those "new" substances had to be registered under the European List of Notified Chemical Substances (ELINCS).[74] This distinction failed to adequately account for the environmental and human health effects from those "existing" substances, and the assessment of the risks of the "existing" substances proved slow in coming and incomplete when arrived.[75]

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terial resistance and endocrine disruption. *Id.* Ethylene oxide is a base substance used to formulate other substances that act as emulsifiers, surfactants, thickeners and humectants; it is an essential substance to formulate cosmetic products. *Id.* Formaldehyde is found in nail hardeners and one of the critical starting materials for Reppe chemistry, used to create preservatives, hari fixatives, thickeners and solvents. *Id.* Many of these companies may eventually be placed on the SVHC list. *See* Rivlin et al., *supra* note 8 (discussing ability of ECHA to add substances onto SVHC list).

70. *See* Council Regulation 1907/2006, Annex XVII, REACH, 2006 O.J. (L 396) 395 (EC) (listing and restricting substances and articles from being manufactured or being placed on market). These chemicals, either on their own or in a particular use, have already been banned from being manufactured in or imported into Europe before REACH was enacted, and are therefore listed in REACH as already banned substances. *Id.*

71. *See id.* (listing and restricting prohibited substances and articles); *see also* Rivlin et al., *supra* note 8 (noting substances subject to restriction under Annex XVII).

72. *See* Bowman & van Calster, *supra* note 27, at 376 (defining "existing" substances according to previous European legislation). The list can be found on the European Inventory of Existing Commercial Chemical Substances ("EINECS"), and includes more than one hundred thousand substances. *Id.*

73. *See id.* (defining "new" substances according to previous European legislation). There are over four thousand "new" substances presently on the market. *Id.*

74. *See id.* (detailing previous classification of substances); *see also* ENV'T DIRECTORATE GEN., *supra* note 36, at 3 (detailing previous classifications of substances).

75. *See* ENV'T DIRECTORATE GEN., *supra* note 36, at 3 (discussing previous classifications of regulations); *see also* Bowman & van Calster, *supra* note 27, at 376 (discussing previous classifications of regulations). Even though there was a fixed

Though the "new" substances were tested before they were placed onto the market under the former method, the largest drawback was that the "existing" substances were not tested.[76] The data on the safety of, or serious or substantial harm being caused by, "existing" substances to the environment and human health was and would be, needless to say, quite lacking.[77]

REACH eliminates this distinction.[78] The regulation streamlines the requirement that *all* substances, either manufactured in or placed onto the European market, undergo registration, evaluation and, perhaps, authorization.[79] Though REACH gives previously considered "existing" substances a longer registration period, for administrative reasons, the ECHA will eventually have studied all thirty thousand substances on the European market.[80]

b. Element #2: Articles

There is more in the experiment than just substances: REACH reacts products, or articles, with substances.[81] Articles are "object[s] which during production [are] given a special shape, surface or design which determines [their] function to a greater degree than does [their] chemical composition."[82] In other words, articles contain the chemical, and intend to release the chemical "during normal and foreseeable conditions of use."[83] This distinction is important, as articles are anything ranging from cars to lipstick; this provision potentially covers sectors such as the automotive, pharmaceutical, cosmetic and electronic industries, amongst others.[84]

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date in determining "existing" or "new" substances, the distinction was historical and arbitrary. *Id.*

76. *See* ENV'T DIRECTORATE GEN., *supra* note 36, at 3 (showing problem with old regulation).

77. *See id.* (noting result of problem with old regulation).

78. *See id.* at 15 (noting REACH's elimination of old classifications).

79. *See id.* (describing simplification of European chemical regulation).

80. *See* ENV'T DIRECTORATE GEN., *supra* note 36, at 4, 5, 15 (describing protocol of "existing" and "new" substance registration under REACH and REACH's impact on elimination of old substance classification); *see also* Rivlin et al., *supra* note 8 (noting longer timetable for "existing" substances than "new" substances). The reason to allow a longer timescale for "existing" substances is to reduce the administrative burden on both the ECHA and the industry that will come from attempting to compile data for "existing" substances, which is substantially less than that for "new" substances. *Id.*

81. *See* Council Regulation 1907/2006, art. 3.3, REACH, 2006 O.J. (L 396) 54 (EC) (defining articles).

82. *See id.* (defining articles).

83. Rivlin et al., *supra* note 8 (noting REACH requires registration of substances in articles).

84. *See id.* (discussing impact of REACH on industries that manufacture articles).

c. Element #3: Downstream users

The final basic element found in the REACH experiment is the "downstream user."[85] A "downstream user" is "any natural or legal person established within the [European] Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities."[86]

Downstream users do not have to register substances or articles themselves, as only the manufacturer of a substance or article has the obligation to do so.[87] While downstream users are free from the entanglements of direct REACH compliance, they are still faced with several responsibilities, including ensuring that their potential future use of the substance is covered in the "exposure scenario" (ES).[88] The downstream user's supplier—the manufacturer or importer in charge of registering the substance under REACH—files the ES.[89] If the downstream user's substance is not covered under REACH, it must either find another supplier whose substance is covered, or register its products on its own behalf and file its own safety report with the ECHA.[90]

Possible supply problems are a final economic obstacle REACH places before downstream users.[91] European subsidiaries of foreign companies, who anticipate using specialized substances in manufacturing products for the European market, must ensure that their supplier registers the substances under REACH.[92]

85. *See id.* (noting downstream users' role and obligations under REACH).

86. Council Regulation 1907/2006, art. 3.13, REACH, 2006 O.J. (L 396) 53 (EC) (defining downstream user). Downstream users do not include either distributors or consumers. *Id.*

87. *See* Council Regulation 1907/2006, art. 3, REACH, 2006 O.J. (L 396) 53 (EC) (defining downstream user as distinct from manufacturer or importer); *see also* Rivlin et al., *supra* note 8 (describing and defining downstream users); *see also* European Chemicals Agency, *Guidance for Downstream Users* 13-14 (2008), *available at* http://guidance.echa.europa.eu/docs/guidance_document/du_en.pdf?vers=29_01_08 (describing obligations of downstream users).

88. *See* Rivlin et al., *supra* note 8 (discussing further obligations of downstream users). The ES is found in their supplier's safety report or data sheet. *Id.*

89. *See id.* (discussing ES obligations).

90. *See id.* (discussing options for downstream users in face of failed ES); *see also* European Chemicals Agency, *Guidance for Downstream Users*, Apr. 17, 2008, *available at* http://echa.europa.eu/doc/reach/080417%20ECHA_08_GF_02-EN_Downstream_User.pdf (describing procedures for downstream users).

91. *See* Rivlin et al., *supra* note 8 (discussing supply problems posed by REACH).

92. *See id.* (discussing European subsidiary obligations to register specialized substances). Downstream users should be assessing the substances they use and confirming that their suppliers are taking appropriate steps to comply with REACH. *Id.*

III. TWO DIFFERENT EXPERIMENTS: ANALYSIS OF THE AMERICAN AND EUROPEAN MODELS

REACH is "the latest and perhaps the most visible evidence of a growing trend toward greater global regulatory requirements for industry-led evaluation and understanding of the risks of chemical exposure and effects in the environment" of our time.[93] From the United States' perspective, the most important and challenging aspect of such legislation is the diametric procedural and substantive shift from the United States' chemical regulation experiment—the Toxic Substances Control Act of 1976 (TSCA)—to REACH; this shift is exemplified by at least two facets: the elimination of outdated chemical categories and shifting the burden onto the industry.[94] REACH has been seen by some as a legislative critique of the TSCA and an attempt by Europe to enact the antithesis of the United States' toxic chemicals regulation.[95]

A. The United States Experiment: Toxic Substances Control Act of 1976 (TSCA)

Five years after an original legislative proposal, the United States' Council on Environmental Quality (CEQ) proposed a new

93. Beth Sirull, *Prepare Now for REACH Compliance*, CHEM. ENG'G PROGRESS, Mar. 2005, at 45, *available at* http://www.erm.com/erm/Website.nsf/GFN/ERM-REACH-March%202005.pdf/$file/ERM-REACH-March%202005.pdf (understanding purpose and effect of REACH).

94. *See* Farber, *supra* note 14, at 21 (discussing features of REACH different from TSCA). Because Europe was reinforced by the American experience, REACH has two fundamental principles inapposite from the TSCA. *Id.* The first is that Europe found the distinguishing between old and new chemicals inadequate. *See id.* Secondly, Europe found the placing of the burden of proof on the agency to establish unreasonable risk of the contested substances inadequate as well. *Id.* The result was a regulation in Europe fundamentally opposite to its American counterpart in two very important aspects. *See* John S. Applegate, Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform 3 (July 28, 2008) (unpublished working paper, on file with the University of Indiana University School of Law – Bloomington Indiana Law Journal), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1183942 (noting failures of TSCA approach led to negation in REACH); *see generally* Karkkainen, *supra* note 44, at 1432-34 (discussing burden shifting and removal of classification on when substances came onto market to remove perverse incentives).

95. *See* John S. Applegate, *Bridging the Data Gap: Balancing the Supply and Demand for Chemical Information*, 86 TEX. L. REV. 1365, 1390 (2008) (discussing TSCA as cautionary tale for Europe and how REACH is anti-TSCA in many ways); *see also* Applegate, *supra* note 94, at 2-3 (describing Europe's response to studies of chemical regulation). REACH stems from the so-called "White Paper," a parallel to the *Toxic Substances* paper, written before the TSCA was passed, finding a need for the TSCA. *Id.* Europe's "White Paper" was a stinging critique of American chemical regulation and the results suggested that Europe should enact REACH as a product of that critique. *Id.*

approach to federal chemical regulation, which Congress passed as the Toxic Substances Control Act of 1976 (TSCA).[96] The TSCA allows manufacturers to submit a list of chemicals (which potentially require regulation) to the Environmental Protection Agency (EPA), and it is the EPA that determines whether or not the chemicals can be placed onto the market.[97] The TSCA also requires manufacturers to register chemicals placed onto the market only after January 1, 1980, and are manufactured in volumes of more than ten kilograms per year; these chemicals alone are subsequently reviewed by regulators.[98]

The effectiveness of the TSCA, in light of comprehensive industrial chemical regulation envisioned by the CEQ, has undoubtedly fallen short.[99] The intended purpose of the TSCA was "to prevent 'unreasonable risks of injury to health or the environment' associated with manufacture, processing, distribution, use or disposal of chemical substances other than drugs or pesticides."[100] The CEQ had focused on health and environmental effects when it proposed a reassessment of the United States' chemical regulation; yet

96. *See* Applegate, *supra* note 93, at 2 (describing purpose of TSCA). CEQ's findings, *Toxic Substances*, identified major problems in the then-current chemical regulation, such as gaps left by the media-based pollution statutes, lack of opportunity to prevent pollution, and lack of adequate information concerning the effects of substances. *Id.* at 3 (describing CEQ's concerns); *see also* Richard M. Nixon, President of the United States, Special Message to Congress Proposing the 1971 Environmental Program (Feb. 8, 1971) (transcript *available at* http://www.presidency.ucsb.edu/ws/index.php?pid=3294) (addressing Congress concerning state of nation's environment). President Nixon referred to CEQ's findings in proposing the EPA to take charge of what eventually became the TSCA. *Id.*

97. *See* Applegate, *supra* note 94, at 3-7 (describing function of TSCA in U.S. chemical industry). At the time of *Toxic Substances*, Congressional findings determined that the results of environmental exposure to vast majority of chemicals was inconclusive, and therefore the TSCA should be a preventive measure with both the environmental and economic implications on the chemical industry taken into account. *Id.* at 6, n.15 (discussing Congressional findings). The TSCA, therefore, was enacted without much bite, as it left up to the manufacturers themselves to disclose the potential harmful data of their own chemicals, and many chemicals were either grandfathered in or regulated by other pieces of legislation, such as the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). *Id.* The legal burden, furthermore, was on the EPA to demonstrate the "*un*safety" of a potentially harmful chemical. *Id.* at 15.

98. *See* TSCA 15 U.S.C. §§ 2601-2604 (presenting parameters of chemical regulation); *see also* Sirull, *supra* note 93, at 47 (discussing differences between TSCA and REACH). For chemicals in existence on the market before 1980, the TSCA presumes them safe, unless the government can prove otherwise. Sirull, *supra* note 93, at 47. For new chemicals, manufacturers must file a Pre-Manufacture Notification (PMN), disclosing available toxicity data, which undergoes EPA review. *Id.*

99. *See* Applegate, *supra* note 94, at 11 (discussing disappointments of TSCA).

100. TSCA § 2601 (noting purpose of legislation); *see also* Farber, *supra* note 14, at 8 (noting intended purpose of TSCA).

by the time the CEQ's proposal made its way through the halls of Congress, the TSCA as originally envisioned was "highly compromised," due to concern over the regulation's economic impact on the chemical industry, upon which the United States relied heavily during the 1970s.[101]

The EPA lost much of its power in the subsequent judicial interpretation and timid implementation of the TSCA, particularly the clauses establishing the EPA's standard of review for potentially dangerous chemicals and the types of reviewable chemicals under the TSCA.[102] Judicial interpretation followed the policies set forth by the TSCA,[103] and these policies undeniably favored the chemical industry's economic interests.[104] Under the existing legal standard, the EPA "can only act to restrict an existing chemical after demonstrating that it poses an 'unreasonable risk'" of injury to health or the environment, and "[e]ven then, the remedies imposed must be the 'least burdensome' to achieve the intended results."[105] In 2005,

101. *See* Farber, *supra* note 14, at 2, 11 (discussing final version of TSCA and Congress's reasons for different focus than *Toxic Substances*).

102. *See id.* at 2 (noting EPA's loss of power over time in regulating chemicals).

103. *See* TSCA § 2601(b) (outlining policy of TSCA); *see also* Farber, *supra* note 14, at 8 (describing three policies of TSCA). The TSCA sought data to be developed on the environmental effects of chemicals, with that responsibility on the industry, meaning that the industry controls the data development. Farber, *supra* note 14, at 8. Next, the government should have "adequate" authority to prevent unreasonable risks of injury to health or the environment, but that authority is limited. *Id.* Finally, the limit is that the authority should be exercised "so as 'not to be impeded unduly or create unnecessary economic barriers'" to the chemical industry. *Id.*

104. *See* Press Release, Lowell Center for Sustainable Production, Chems. Policies in Eur. Set New Worldwide Standard Registration, Evaluation and Authorization of Chems. (REACH) (Oct. 10, 2003), http://www.chemicalspolicy.org/downloads/10-03_chemicals_policy_reach.pdf (noting value of United States chemical industry in 2003 at $20 billion).

105. *See* TSCA § 2605 (discussing unreasonable risk). The "unreasonable risk" standard leaves the TSCA "blind and toothless." *See* Daryl Ditz, *Cloudy Skies, Chance of Sun: A Forecast for U.S. Reform of Chemical Policy*, CIEL REP. (Center for Int'l Envtl. L., Washington, D.C.), adapted from *A Forecast for U.S. Reform of Chemical Policy*, May 9, 2006, at 2, *available at* http://www.ciel.org/Publications/Cloudy_Skies_9May06.pdf (noting TSCA's built-in disincentives for generating safety data). The "unreasonable risk standard is the central regulatory standard of the TSCA, but is undefined in the statute, but judicial interpretation "consistently interpret it as a greater-than-zero level" by a range of factors, "including direct and indirect costs." *See* Applegate, *supra* note 94, at 4, 8 (discussing unreasonable risk). The EPA, furthermore, can only get information on chemicals that pose a "substantial risk" of "unreasonable harm"; since risk denotes potential for harm, not actual harm, and the TSCA leaves it to the manufacturers to determine whether a chemical poses a "substantial risk," the EPA cannot get information on whether a certain chemical bears an "unreasonable risk" of "substantial harm" if it is not submitted to the EPA for review. *See id.* at 11-13; *see also* Farber, *supra* note 14, at 12 (discussing TSCA's trigger of regulatory provisions).

the Government Accountability Office (GAO) reported that "only about [twenty] percent of new chemicals received detailed review."[106] Due to the unavailability of data under its standard of review, the EPA has only been empowered to test two hundred of the thousands of existing chemicals placed on the market since the TSCA has been enforced, and none since 1990.[107] The "grandfathering in" clause, meanwhile, has resulted in classifying more than ninety-five percent of all "chemicals on the market today [as] 'existing' chemicals [if introduced before January 1, 1980], thereby [allowing chemicals to] escap[e] even the minimal scrutiny applied to 'new' chemicals" that were to be regulated by the TSCA.[108]

B. The Experiments Compared: REACH vs. TSCA

REACH proposes to counter the TSCA in several ways, including eliminating the distinction between "existing" and "new" chemicals and shifting the burden of proof away from government (to prove a substance is unsafe) onto the manufacturer (to prove a substance is safe).[109] Responding to the perceived failures of the TSCA,

> REACH does away with the arbitrary classification of chemicals based on the date they came to market, replacing it with a categorization based on volume usage and hazardous properties vis-à-vis intended use. While TSCA requires significant information only on chemicals new to the market since 1980, REACH requires information for all chemicals where current annual usage exceeds [one metric ton].[110]

Eliminating the "old-new" distinction "remed[ies] the 'burden of the past'"; in other words, the ECHA is required to examine *all* existing chemicals on the market, to categorize and evaluate them

106. *See* Ditz, *supra* note 105, at 2 (discussing GAO's 2005 findings).

107. *See* Applegate, *supra* note 94, at 12-13 (noting GAO findings and data on existing chemicals).

108. *Id.* (discussing problems with TSCA). For a further discussion of TSCA's "grandfathering in" of previously existing chemicals, see David Wirth, *The EU's New Impact on U.S. Environmental Regulation*, 31 FLETCHER FORUM OF WORLD AFFAIRS 91, 101-02 (2007) (noting TSCA's reliance on "unreasonable risk" leaves ninety-five percent of chemicals on market to never undergo toxicity testing).

109. *See* Applegate, *supra* note 94, at 21-26 (showing REACH as antithesis of TSCA).

110. Sirull, *supra* note 93, at 47 (noting differences between TSCA and REACH).

in order to determine which ones carry the burden of registration, and to pass the determination on to the manufacturers.[111] REACH forces the manufacturer to both produce information relating to the substance and prove the safety of the substance itself, a result opposite to the TSCA's placement of burden.[112]

REACH, as the "antithesis" of the TSCA, has caused great concern among American companies that need to comply with the regulation if they desire continued access to the European market.[113] The net result is that REACH forces many manufacturers, both globally and particularly domestically, to reformulate their products for sale, while it streamlines chemical regulation in the European Union, thus "turn[ing] the highest available standard into the world's common denominator."[114]

IV. THE YIELD FROM THE REACTION: FUTURE IMPACT

The results from the European laboratory leave a different scent in the noses of the participants, dependent upon whether the participant is a member of government or a member of the chemical industry, and further dependent on which side of the Atlantic the party finds itself. From the European Union's perspective, REACH will undoubtedly attain its lofty goals and, by setting the bar so high, will create a base threshold of chemical regulation that other jurisdictions will strive to emulate.[115] The European chemicals industry, furthermore, will benefit from a uniform system of regulation, leading to a more systematic method of risk evaluation, greater consumer confidence, stimulation of both innovation and information access, and an enormous cost savings over the coming

111. *See* Applegate, *supra* note 94, at 23 (discussing REACH's interpretation of old and new chemicals).

112. *See* Council Regulation 1907/2006, art. 5, REACH, 2006 O.J. (L 396) 62 (EC) (denying substances market when substances have not been registered); *see also* Applegate, *supra* note 94, at 23-26 (noting burden of proof). The same lack of data on the hazardous qualities of chemicals encountered by the EPA in enforcing the TSCA drove the development of REACH. Applegate, *supra* note 94, at 24. The EU, however, reached a different conclusion, and because REACH places the burden of providing information and proving safety on the manufacturer, the status quo of "no data, no problem" under the TSCA shifts to "no data, no market" under REACH. *Id.*

113. *See* Applegate, *supra* note 94, at 32 (discussing synthesis between TSCA and REACH for shared ideas and TSCA reform).

114. Layton, *supra* note 22, at A1 (discussing manufacturers' responses to REACH); *see also* Bowman & van Calster, *supra* note 27, at 376 (discussing eventual global regulatory impact of REACH).

115. *See* Bowman & van Calster, *supra* note 27, at 382 (detailing benefits of REACH).

decades.[116] Other chemical industries, in the United States for example, fear that the cost of implementing REACH may outweigh its benefits, in both the short and long term.[117] Some parties in the United States, however, have noted that the fear over REACH's potentially toxic impact has been overblown.[118] But for those various industries that can smell odorous fumes emanating from the European laboratory, either in Europe, the United States or elsewhere, the acrid stench of the financial and administrative burden of REACH compliance is pungent.[119]

A. The European Laboratory's Perspective

The European Union has effectively surpassed the United States as the global leader in chemical regulation with the implementation of REACH.[120] In passing the legislation, the European Parliament affirmed that any potentially objectionable costs or undesirable noxious effects posed by REACH are outweighed by the regulation's nontoxic benefits.[121]

1. Positive Reaction: Benefits

Studies have shown that REACH will reduce both the number of chemicals released into the environment and the human harm caused by exposure to those chemicals.[122] Though comprehensive quantitative assessment is limited, the preliminary outlook of

116. *See id.* (detailing benefits of REACH). REACH will encourage innovation in the industry, streamline the regulatory process, and produce significant health and safety benefits for citizens and the environment. *Id.* Europe anticipates healthier workers and saving future costs in pharmaceuticals. *See* Amy Goodman, *Toxins 'R' Us*, TRUTHDIG, Feb. 24, 2009, http://www.truthdig.com/report/item/20090224_toxins_r_us/ (noting cost savings in Europe over long term application of REACH).

117. *See* Layton, *supra* note 22, at A1 (noting United States opposition to REACH). The United States chemical industry and the Bush Administration spent eight years vigorously opposing REACH, arguing that the burden of the regulation on manufacturers would outweigh any public benefit. *Id.*

118. *See* In-pharmatechnologist.com, http://www.in-pharmatechnologist.com/Industry-Drivers/REACH-impact-claims-overblown-says-Tufts-study (last visited Mar. 5, 2009) (noting Tufts University study).

119. *See* Bowman & van Calster, *supra* note 27, at 381 (discussing costs borne by chemical industry).

120. *See* Farber, *supra* note 14, at 1 (noting Europe's emerging leadership in environmental regulation).

121. *See* ENV'T DIRECTORATE GEN., *supra* note 36, at 15 (discussing costs and benefits of REACH).

122. *See id.* at 15-16 (discussing environmental and health benefits of REACH).

REACH's impact on the environment is positive.[123] When fully implemented, REACH should contribute to a reduction in not only air, water and soil pollution but also pressure on biodiversity, improve control over toxic substances and ensure they are prevented from polluting the environment.[124] This, in turn, will have a positive impact on human health, as contact with these substances and articles has been linked to certain respiratory problems, eye disorders and skin diseases, such as those found near Seveso after 1976.[125]

2. Negative Reaction: Costs

REACH's costs come mainly in the economic sector; the Extended Impact Assessment estimated the direct costs of REACH to the chemical industry at a total of over two billion Euros, without specifically calculating the other various indirect costs to downstream users.[126] The total anticipated cost of REACH, however, is not expected to exceed much more than five billion Euros over a fifteen year period, or roughly equal to the same amount of money that one European country planned to spend to "bail out" an automobile manufacturer's European division in March 2009.[127]

This is where REACH could trip over a stumbling block, though; in the wake of the 2007-2009 global financial meltdown, firms around the world may adjust accordingly, feeding a fear that capital, which should go to environmental regulation compliance, may instead be steered toward rescuing the financial system.[128] The

123. *See id.* at 16 (noting limited amount of cases and lack of data). Though the amount of data is lacking, studies have shown that the long-term effects of REACH will be significant. *Id.*

124. *See id.* (listing long-term benefits of REACH).

125. *See id.* at 15 (listing benefits of REACH on human health).

126. *See* ENV'T DIRECTORATE GEN., *supra* note 36, at 16 (noting direct costs and costs to downstream users of REACH). The estimate is projected through the last day of registration in 2018. *Id.*

127. *See id.* at 15 (discussing total costs of REACH); *see also* Tristana Moore, *Should Germany Help Bail Out GM?*, TIME, Mar. 14, 2009, http://www.time.com/time/business/article/0,8599,1885112,00.html (discussing proposal of Opel bailout). In March 2009, the German government planned to use approximately five billion Euros to bailout General Motors Europe's Opel division. *Id.* For a further discussion of the GM-Opel bail out, *see* David Crossland, *Opel Bailout Poses Major Risks for Berlin*, SPIEGELONLINE INT'L, Feb. 18, 2009, http://www.spiegel.de/international/germany/0,1518,608402,00.html (discussing proposed bailout); *see also* Matthew Curtin, *GM Bows to Berlin Over Opel Bailout*, WALL ST. J., Sept. 11, 2009, http://online.wsj.com/article/SB125260438598600301.html (discussing GM sale of Opel division to Magna International).

128. *See* Ass'n of Chartered Certified Accountants, *How Should the EU Respond to the Current Financial Crisis* at 7, Feb. 5, 2009, *available at* http://www.accaglobal.com/pubs/publicinterest/pressandpolicy/unit/european_briefings/financial_cri-

European Union also faces competition from Asia, where chemical regulation is virtually nonexistent and whose chemical markets are quickly growing and will imminently be larger than those of the United States or Europe.[129] To combat both the economic crisis and competitively priced chemical exports from regions such as the Middle East and Southeast Asia, many European firms are putting a "focus on high-value products, further strengthen[ing] customer relationships, invest[ing] in overseas firms and look[ing] to consumer demand for greener products as an opportunity to innovate to find new product markets."[130] The ECHA, meanwhile, is advising Asian firms on the compliance benefits of REACH to their markets; some Asian countries, in fact, have already begun creating similar regulations, even in the face of economic uncertainty.[131] In Europe, Asia and North America, moreover, investment in cleaner chemical technology has reached an all-time high, in spite of the economic downturn.[132]

B. The American Laboratory's Perspective

The view from the American laboratory is quite different. Companies in the United States have been, continue to be and will be severely affected by NGO pressure to voluntarily follow REACH's provisions domestically, not to mention the need to actually follow REACH when transacting in Europe.[133] While some environmental activists are thrilled with the new legislation, others may continue to press the European Union to include even more chemicals on its banned list, thereby further harming the American chemical indus-

sis.pdf (discussing current financial crisis impact on environmental policy in Europe).

129. *See* Patel, *supra* note 13 (discussing current economic crisis impact on European chemical industry).

130. *Id.* (detailing European response in current economic crisis).

131. *See id.* (discussing ECHA and Europe's offering of insight and expertise to Asia). The ECHA is meeting with Asian chemical industry leaders to discuss the future of European and Asian interaction in the chemical industry and the benefits of the European system. *Id.* Japan and South Korea, furthermore, have started the process of enacting REACH-style legislation. *Id.*

132. *See* Tanzco Mgmt. Consulting, LLC, Green Chemistry 2009, http://www.tanzco.net/html/green_chemistry_2009.html (noting high investment in green technology in 2008 third quarter). Investment in these companies reached historic levels in both Europe and the United States, where firms recorded investments of $742 million and $1.75 billion, respectively. *Id.* In 2005, sales of chemicals in the E.U. totaled an astounding _436 billion, excluding pharmaceuticals. *See* Bowman & van Calster, *supra* note 27, at 380 (discussing sales of chemicals in Europe).

133. *See* Steinberg et al., *supra* note 68 (describing NGO reaction to REACH in USA).

try.[134] The current list of SVHCs, however, let alone REACH's entire list of dangerous substances, has already begun posing headaches for the industry,[135] in both the financial and labor sectors.[136]

The United States now faces an enormous challenge, as it must overhaul its own laws on toxic chemical regulation to respond to the European legislation.[137] REACH affects not only chemicals, but also products containing those chemicals; and not only products manufactured in Europe by American companies, but also products made outside of and exported to Europe.[138]

1. The Current State of American Experimentation

Historically, the United States has relied too heavily upon chemicals that are either now completely banned in Europe or are found on the SVHC or SIN lists.[139] Globally, eighty-five "SIN list chemicals are produced annually in amounts of one million or more pounds, and at least [fourteen] exceed one *billion* pounds annually."[140] In the United States, moreover, eight states produce or

134. *Compare* Cone, *supra* note 11, at A12 (noting activists' response to REACH), *with First REACH Hazardous Chemicals Identified*, GREENPEACE, Oct. 9, 2008, http://www.greenpeace.org/eu-unit/press-centre/press-releases2/First-REACH-hazardous-chemicals-identified (noting need to address shortness of REACH Candidate List). Many activists have chided the United States for falling behind Europe in regulating chemicals, and hope that REACH will lead to safer products in both Europe and the United States. Cone, *supra* note 11, at A12. While there are only fifteen substances on the Candidate List, there are hundreds of known hazardous chemicals in use, and should be addressed if the EU is to be taken seriously in its protection of the environment and human health through REACH. *See First REACH Hazardous Chemicals Identified*, *supra* note 134 (listing substances on candidate list).

135. *See* Commondreams.org, US Chemical Companies Will Be Impacted by REACH, *www.commondreams.org/print/32947* (last visited Mar. 13, 2009) (noting direct effect of REACH on American companies). Hundreds of companies in thirty-seven of the fifty states produce or import hundreds of chemicals that the EU has designated as dangerous. *Id.*

136. *See* Farber, *supra* note 14, at 2 (noting REACH's extensive impact on American chemical industry). REACH not only impacts 14 billion dollars worth of United States chemical exports per year, but also 54,000 jobs. *Id.*

137. *See* Cone, *supra* note 11, at A12 (noting American response to REACH). Spurred on by REACH, the United States is finally facing the need to change certain toxic chemical laws in order "[t]o protect the health of Americans and the competiveness of U.S. companies . . . ." *Id.*

138. *Id.* (noting impact of REACH on chemical industry and beyond).

139. *See* Nixon, *supra* note 96 (addressing United States' overuse of chemicals); *see also* Peter Waldman, *Common Industrial Chemicals in Tiny Doses Raise Health Issue*, WALL ST. J., Jul. 25, 2005, at A1 (discussing chemicals commonly found in United States).

140. Commondreams.org, *supra* note 135 (listing findings of EDF's report).

import at least a dozen SIN list chemicals.[141] The challenge of compliance seems to rest, above all, with the chemical industry in the United States, as three of the five companies producing the most SIN list chemicals are headquartered in America.[142] Due to the "grandfathering in" of a substantial number of chemicals covered by the TSCA, many of these chemicals, which will be subject to REACH if imported to Europe, have not been subjected to regulation or even tested for safety in the United States.[143] Only about one-third of the SIN list chemicals, in fact, have even been subjected to testing by the TSCA, leaving an enormous gap to close in terms of identifying and preparing to register highly suspect substances.[144]

Despite this, numerous large American companies have begun establishing strategies to prepare their substances and articles for REACH compliance.[145] The majority of companies in the American chemical industry, however, still face a substantial uphill battle, having spent much of President George W. Bush's administration adamantly opposing the new regulation and complaining of the cost of compliance, rather than exploring viable alternatives or thoroughly preparing to comply with REACH.[146] The entirety of the chemical industry is affected by REACH, and rejecting the regu-

141. *See id.* (noting United States' contribution to SIN list). The eight states are: New Jersey, Texas, Louisiana, Ohio, New York, North Carolina, Kentucky and Michigan. *Id.*

142. *See id.* (listing findings of EDF's report). The five chemical companies are Dow, DuPont, Chemtura, Equistar (the Netherlands) and BASF (Germany). *Id.*

143. *See* Layton, *supra* note 22, at A1 (discussing chemicals grandfathered under TSCA). About 62,000 chemicals did not have to be tested after TSCA was passed in 1976. *Id.* While companies were required to report toxicity reports for these chemicals to the government, of the roughly 80,000 chemicals on the U.S. market, only 200 of them have been studied additionally for possible toxicity. *Id.*

144. *See* Richard Denison, *Across the Pond: Assessing REAH's First Big Impact on U.S. Companies and Chemicals*, Envtl. Def. Fund, Jan. 2009, at 14, *available at* http://www.edf.org/documents/8538_Across_Pond_Report.pdf (finding TSCA has only identified one third of SIN List chemicals).

145. *See* Rivlin et al., *supra* note 8 (discussing manufacturers' REACH compliance).

146. *See* Layton, *supra* note 22, at A1 (discussing government and chemical industry reaction to REACH). The U.S. chemical industry and four agencies (the EPA, the Commerce Department, the State Department and the Office of the Trade Representative) spent eight years vigorously opposing REACH, claiming there would be a great burden on the manufacturers, not balanced by any public benefit. *Id.* For example, DuPont anticipates spending "tens of millions" of dollars to just register five hundred chemicals with ECHA. *Id.*

lation means, whether the industry agrees or not, the loss of a market and enormous economic repercussions.[147]

2. Redesigning the American Laboratory

On the opposite end of the spectrum, one environmental group has now urged the United States government to implement REACH-style legislation, arguing that REACH will become the standard for chemical regulation in the future.[148] Though the TSCA differs with REACH in several areas of review, an executive with the group opines that REACH will heighten information sharing and affect how the market handles the new standards of chemical review.[149] Some have also argued that the TSCA has been preventing chemical innovation by encouraging the continued use of old and more dangerous technologies.[150]

NGO involvement has resulted in pressure on Congress, which heightened during the Bush Administration, to revisit the TSCA; going forward, NGOs will continue to press for change in the United States' toxic chemical laws, including drastic improvements to, or a replacement for, the TSCA.[151] Despite the economic downturn in 2007-2009, this change may be affected by the election of President Barack Obama, who alluded to imposing stricter chemical regulations during his Administration.[152] The Obama Adminis-

147. *See id.* (noting ninety percent of U.S. chemical industry is affected by REACH). Chemical companies must comply with REACH or lose access to twenty-seven countries and five hundred million people. *Id.*

148. *See* Joe Kamalick, *Environmental Group Urges U.S. Adoption of REACH*, ICIS, Apr. 4, 2007, http://www.icis.com/Articles/2007/04/04/9018731/environmental-group-urges-us-adoption-of-reach.html (discussing Environmental Defense Fund report). The report urges the United States to adopt most of REACH's chemical control program, to replace the TSCA. *Id. See also* Richard Denison, *Not that Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals*, Envtl. Def. Fund, Apr. 2007, at VII-14, *available at* http://www.edf.org/documents/6149_NotThatInnocent_Fullreport.pdf (detailing Defense Fund's urging of United States' adoption of REACH-like policies).

149. *See* Kamalick, *supra* note 148 (discussing impact of REACH on United States).

150. *See* Applegate, *supra* note 94, at 22 (arguing TSCA's old-new chemical classification stifles innovation).

151. Steinberg et al., *supra* note 68 (describing NGOs who are pressuring United States to change chemical laws); *see also* Joe Kamalick, *U.S. Should Adopt REACH, Senate Leader Says*, ICIS, Apr. 29, 2008, http://www.icis.com/Articles/2008/04/29/9120117/us-should-adopt-reach-senate-leader-says.html (noting Senator's wish for United States to adopt REACH-like provisions in chemical laws). Senator Barbara Boxer, Chairwoman of the Senate Environment and Public Works Committee, has proposed for legislation to make chemical manufacturers responsible for proving their products safe before they hit the market. *Id.*

152. *See* Tanzco Management Consulting, *supra* note 129 (discussing Obama administration's desire to promote green energy); *but see* Dean Scott et al., *Obama*

tration may in fact lead the way in determining whether the TSCA is still viable in the face of Europe's REACH.[153] Stringent regulations for certain articles similar to REACH, meanwhile, have already been proposed in Congress.[154] These legislators have deemed that the implementation of REACH has rendered inadequate the American strategy of burdening the government, and not the manufacturer, with the responsibility to assess the risks of substances on the market.[155]

3. Should the European Scientists Enter the American Laboratory?

While it can hardly be refuted that the economic cost is the source of its most ardent contention,[156] the chemical industry in the United States is also quick to point out other reasons to be wary of REACH.[157] One firm's executive has insisted that the environmental impact of REACH will not be fully known for years.[158] A scholar has also argued that Europe's adoption of the precautionary principle, though conforming to the Continent's social values, is in truth a method utilized in dominating global chemical regulation and leveling the "global economic playing field."[159] The chem-

Likely to Face Tough Landscape In Effort to Advance Environmental Agenda, 39 ENV'T. REP. 44 (2008), *available at* http://ehscenter.bna.com/PIC2/ehs.nsf/id/BNAP-7L5RBZ (discussing environmental agenda of Obama Administration). The start of the Obama Administration is predicted to be consumed with economic recovery and restoring consumer confidence, mutually exclusive of environmental policy. *Id.*

153. *See id.* (discussing Obama Administration's outlook on chemical regulation).

154. Press Release, Office of Senator Frank Lautenberg, Lautenberg, Solis, Waxman Introduce Legislation to Protect Americans from Hazardous Chemicals In Consumer Products (May 20, 2008), http://lautenberg.senate.gov/newsroom/record.cfm?id=298072 (noting bill proposal). Senator Frank Lautenberg and Representatives Hilda Solis and Henry Waxman introduced the Kid Safe Chemicals Act (KSCA), a proposal for stricter regulation in articles such as toys, in 2008. *Id.* Senator Frank Lautenberg is planning to reintroduce the (KSCA) during 2009. *Id.*

155. *See id.* (discussing inadequacies of United States chemical policies).

156. *See* Cone, *supra* note 11, at A12 (discussing cost of REACH on United States' companies). Europe has already estimated the cost of REACH implementation between two and six billion dollars. *Id.; see also* Press Release, Lowell Center for Sustainable Production, Chemical Policies in Europe Set New Worldwide Standard (Oct. 10, 2003), http://www.chemicalspolicy.org/downloads/10-03_chemicals_policy_reach.pdf (noting impact of REACH on United States' twenty billion dollar chemical industry).

157. *See* Kamalick, *supra* note 148 (noting reply from chemical industry against REACH-style legislation).

158. *See id.* (quoting DeLisi's comments regarding unknown environmental benefits). The concern is that even though the environmental impact will remain unknown, regulation will tie up companies needing to comply. *Id.*

159. *See* Lawrence A. Kogan, *The Extra-WTO Precautionary Principle: One European "Fashion" Export the United States Can Do Without*, 17 TEMP. POL. & CIV. RTS. L.

ical industry, in fact, is wary of the United States adopting REACH-style legislation, in part because, in their view, such regulations would "stifle U.S. chemical and broader industrial innovation and development."[160] Other concerned parties, ranging from chemical interest groups to United States Senators, have urged caution in embracing REACH too quickly, citing failed innovation in Europe.[161] Adopting such regulation in the United States will lead, these critics say, to a lack of both actual burden shifting (away from the government onto the manufacturer) and fear of regulating chemicals on perceived (instead of demonstrated) risk to the environment.[162]

Further opposition to REACH emanates from the consequences of the initial REACH compliance process.[163] The ECHA has planned to group together companies preregistering similar substances, forcing competitors to work together and exchange data if they desire to register their substances.[164] There is a concern that this process will result in companies sharing confidential business information, which would allow access by the EPA and the European Union, the latter being permitted (under REACH) to share that information with other national governments.[165] This

REV. 491, 502 (2008) (arguing Europe is seeking global regulatory and economic dominance in REACH).

160. Kamalick, *supra* note 148 (discussing drawbacks of REACH-style regulation in United States). Jim DeLisi, President of Fanwood Chemical and speaking on behalf of the Synthetic Organic Chemical Manufacturers Association (SOCMA), believes that REACH-like legislation "would not only hamper innovation but reverse progress made over many years by federal regulators . . . ." *Id.*

161. *See id.* (quoting parties opposed to REACH). Parties opposed to REACH include James "Jim" Cooper, Vice-President for Petrochemicals at the National Petrochemical & Refiners Association, and Senator James Inhofe, Republican from Oklahoma and leading global warming skeptic of Congress and ranking minority member of the Committee of Environment and Public Works. *Id.*

162. *See id.* (quoting parties opposed to REACH). Jim Cooper argues that REACH does not shift the burden to manufacturers, since the testing data required still must be evaluated and authorized by a government agency. *Id.* Cooper, furthermore, argues that in the ten-year period since the EU adopted a requirement for premarket testing for new substances, safer chemicals have not been developed and innovation in Europe has been stifled. *Id.* Senator Inhofe argues that the United States should not just run into new regulation based on presumptive, not demonstrated, risk. *Id.*

163. *See* Harvey Black, *Chemical Reaction: The U.S. Response to REACH*, 116 ENVTL. HEALTH PERSP., at A126 (Mar. 2008), *available at* http://www.ehponline.org/members/2008/116-3/EHP116pa124PDF.PDF (last visited Mar. 3, 2009) (noting chemical industry's concern with REACH implementation procedures).

164. *See id.* at A125 (describing preregistration procedures). The substance information exchange forum (SIEF) is a process where the ECHA groups companies together, to avoid duplicating registration of similar substances. *Id.*

165. *See id.* (discussing ACC's concern with REACH). Michael Walls, managing director of health, products, and science policy at the American Chemical

concern is unfounded, however, as not only do the companies control the data exchange themselves, but many of these same companies have urged similar groupings in the past to reduce costs during chemical data testing programs.[166]

The United States has in fact had opportunities to practice complying with REACH-styled regulation, as several states have exercised their right, under the TSCA, "to regulate chemicals that are not already restricted under" it.[167] California, Maine and Massachusetts have been especially active in initiating proposals that have provisions closely resembling REACH.[168] As of 2005, six states had passed legislation restricting certain substances not regulated by the TSCA.[169] In New York, meanwhile, several companies are facing litigation for failing to comply with a New York state law that resembles REACH, requiring manufacturers and sellers of cleaning supplies to disclose data on the environmental and human health harm caused by the substances in such products.[170] Since the im-

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Council (ACC), expressed his concern regarding REACH's implementation procedures. *Id.*

166. *See id.* (expressing confidence in SIEF process and company grouping). Joachim Kreysa, director for cooperation at the ECHA, has noted that the companies not only control the information which they share, but can also opt out of the program, if the data exchange cannot be done without providing confidential business information, as long as they can justify their reasons to the ECHA. *Id.* SIEFs are designed to avoid duplicate or redundant testing, and are similar to groups that domestic companies have formed in the past to avoid similar unnecessary costs. *Id.*

167. Ditz, *supra* note 105, at 4 (noting state chemical regulations).

168. *See* Kogan, *supra* note 159, at 497-98, 555-56 (noting California's seriousness in adopting state law for chemicals regulation resembling REACH and Massachusetts' proposal of legislation styled after REACH); *see also* Ditz, *supra* note 105, at 4 (discussing California's and Maine's proposals). The University of California published a report in March 2006, outlining a comprehensive state-wide regulation policy that had similarities to REACH. Ditz, *supra* note 105, at 4. In February 2006, the governor of Maine established a task force to promote safer alternatives to various substances that would be prohibited by REACH. *Id.* California is considering using REACH as a model for all future chemical regulation. *See* Black, *supra* note 163, at A127 (discussing impact of REACH on California).

169. *See* Ditz, *supra* note 105, at 4 (discussing state restrictions on chemicals). Substances that the states restricted or consider restricting, which are not restricted nationally, include certain brominated flame retardants and certain mercury-containing products. *Id.*

170. *See* Press Release, Earth Justice, Manufacturers Flout Law, Refuse to Disclose Toxics in Household Cleaners (Feb. 17, 2009), *available at* http://www.earthjustice.org/news/press/2009/manufacturers-flout-law-refuse-to-disclose-toxics-in-household-cleaners.html (discussing chemical manufacturers' opening to litigation for flouting New York law). Earth Justice is litigating against Proctor & Gamble, Colgate-Palmolive, Church and Dwight, and Reckitt-Benckiser, on behalf of various environmental and consumer rights groups, for failure to disclose the effects of the chemicals that make up their products. *Id.*

plementation of the law not a single company has complied.[171] Noting Justice Brandeis' oft-quoted aphorism, REACH-type chemical regulation may eventually come to the United States through the leadership of individual states' acting as the "laboratories of democracy."[172]

In a response to REACH, the EPA has developed the Chemical Assessment and Management Program (ChAMP), the result of a commitment, made by the United Sates, Mexico and Canada in August 2007, to cooperate in the safer manufacture of industrial chemicals.[173] ChAMP, the North American attempt to keep pace with REACH, has come under criticism, even though it attempts to characterize screening-level hazard and risk for thousands of chemicals by 2012.[174] Some opine that ChAMP, in its rush to answer the growing global criticism of the United States' chemical regulation, will both yield less data on fewer chemicals than the TSCA already does and use poor quality information to make decisions about the risk of certain chemicals' use.[175] Even the critics conclude, however, that while ChAMP is flawed, it contains enough positive aspects that it would help guide the United States' regulatory scheme in playing catch-up with the international community.[176]

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171. *See id.* (observing lack of compliance with New York state law).

172. *See id.* (concluding states' leadership role in revisiting and remodeling United States' chemical regulation); *see also* New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (commenting on states' roles in federal system in trying novel economic and social experiments in legislation).

173. *See* Farber, *supra* note 14, at 12 (describing EPA's response to REACH); *see also* Environmental Protection Agency, Chemical Assessment and Management Program, http://epa.gov/champ/ (last visited Mar. 3, 2009) (outlining EPA's response to REACH).

174. *See* Farber, *supra* note 14, at 12 (discussing ChAMP criticism); *see also* Chemical Assessment and Management Program, *supra* note 173 (proposing purpose and action of ChAMP).

175. *See* Farber, *supra* note 14, at 12 (discussing criticism of ChAMP). ChAMP's shortcomings include lack of transparency in describing the information already possessed by the EPA, failure to fill gaps in safety data the EPA has already identified, overestimating the number of high-volume chemicals for which the EPA supposedly already has data, and relying too heavily on information provided by manufacturers. *See* Press Release, Environmental Defense Fund, ChAMP Just Doesn't Have the REACH (May 2, 2008), http://www.edf.org/pressrelease.cfm?contentID=7873 (discussing failings of ChAMP).

176. *See* Press Release, Environmental Defense Fund, *supra* note 175 (discussing impact of ChAMP). Dr. Richard Denison, an EDF Senior Scientist concluded that, though ChAMP does not drag the United States from the TSCA's level of regulation to REACH, it does expand the EPA's testing program to medium production volume chemicals and prioritize them, as well as publically identify chemicals with significant risk. *Id.*

C. Effects on the Catalysts: Industry Impact & Compliance

REACH will affect a plethora of companies, the strength of its impact depending on the particular industry.[177] The chemical industry, for example, is primarily affected as substance manufacturers, while large companies within the industry, such as DuPont or Dow Chemical ("Dow"), have an advantage over smaller manufacturers, as the size of their in-house staff allows them to meet the requirements with more ease and less costs than their smaller competitors.[178] The toy and automotive industries will be affected by REACH just as forcefully as articles manufacturers.[179] REACH will affect even more industries, moreover, such as the cosmetic and energy industries, not only as manufacturers, but also as downstream users, because these industries also use substances and articles to prepare their own products.[180]

There are a variety of ways in which a company can implement REACH compliance, depending on its size, location and industry.[181] Several studies, anticipating such a large economic burden in REACH compliance across industries, offer unique insight into the methods that different REACH-affected companies are using to prepare compliance with the regulation.[182]

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177. *See* YASH Technologies, REACH Impact, http://www.yash.com/reach/reach-chemical-manufacturers-impact.html (last visited Mar. 7, 2009) (listing ways in which REACH affects companies).

178. *See* Black, *supra* note 163, at A125 (discussing United States chemical industry's response to REACH compliance). Dow Chemical, for example, has at least eighteen people who have been hired to work on REACH exclusively as of March 2008. *Id.*

179. *See* Louis Wyness, *Impact of REACH on US Exporters of Manufactured Goods to the EU*, THE MFR. (Feb. 7, 2007), http://www.themanufacturer.com/us/detail.html?contents_id=5230 (discussing REACH registration of household items, such as toys, as articles under REACH).

180. *See* The European Cosmetic Association, The Impact of REACH on Cosmetic Manufacturers, http://www.colipa.eu/the-impact-of-reach-on-cosmetic-manufacturers.html?sid=48&smid=126 (last visited Mar. 2, 2009) (describing impact of REACH on cosmetic industry); *see also* Nik Robinson, *How the EU REACH Chemical Regulations Will Impact the Oil and Gas Industry*, ENERGY INT'L, Oct. 2008 at 61, *available at* http://www.energyinternat.com/pdf/444-pdf/444-chem.pdf (discussing impact of REACH on oil and gas industries as downstream users).

181. *See* European Chemicals Agency, *REACH Case Story Summaries*, June 3, 2008, *available at* http://echa.europa.eu/doc/press/press_memo3_en_20080603.pdf (discussing companies' procedures for implementing REACH).

182. *See id.* (separating companies into groups and describing different ways each complies with REACH). The ECHA studied five companies or industries, each very unique in its situation under REACH. *Id.* For a further discussion of REACH's impact on some of these companies and industries and others, see *infra* notes 183-94 and accompanying text.

1. *Catalyst of Element #1: Substances, Dow Europe & the Chemical Industry*

Due to the size of the European chemical industry, companies large and small are bracing themselves for the costs that come with REACH compliance.[183] Dow, a major multinational company with a strong European division (known as Dow Europe), has a large portion of its global manufacturing and sales on the European continent.[184] Dow, like the rest of the chemical industry, as a primary manufacturer and importer of substances, must comprehensively prepare for complying with REACH.[185] Dow has established the Dow Only Representative Trustee (Dow ORT) in order to reduce costs of registering with REACH.[186] Its size and available resources has allowed Dow to implement further measures that ensure compliance will run smoothly at the lowest possible cost.[187]

2. *Catalyst of Element #2: Articles & the Toy and Automotive Industry*

The toy industry is heavily impacted by REACH, as many toys currently on the market contain phthalates, chemicals which were not only already banned in Europe, but were also on the original SVHC list.[188] Many parties are thus concerned that these articles

183. *See* European Chemical Industry Council, Facts and Figures, (Jan. 2009), http://www.cefic.org/factsandfigures/level02/profile_index.html (noting European chemical production in 2007). In 2007, the European chemical industry accounted for €537 billion worth of chemicals sales of the €1820 billion globally. *Id.*

184. European Chemicals Agency, *REACH Case Story Summaries*, June 3, 2008, *available at* http://echa.europa.eu/doc/press/press_memo3_en_20080603.pdf (discussing Dow Chemical's background and approach to REACH compliance). Dow Europe accounts for one third of Dow Chemical's manufacturing, and thirty-seven percent of Dow's annual sales of $54BB are generated in Europe. *Id.*

185. *See* Black, *supra* note 163, at A127 (discussing impact of REACH on chemical industry).

186. *See* Chemie.de, *Dow ORT Cuts Importers' REACH Compliance Costs*, Dec. 5, 2008, http://www.chemie.de/news/e/pdf/news_chemie.de_91525.pdf (discussing Dow's cost-cutting measures for REACH compliance).

187. *See id.* (discussing programs for REACH compliance).

188. *See* European Chemicals Agency, *Substances of Very High Concern, available at* http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp (last visited Mar. 13, 2009) (listing substances requiring authorization). On the list are several phthalates, used in toy manufacturing amongst others. *Id. See also* Waldman, *supra* note 139, at A1 (noting studies linking minute levels of phthalates in toys and cosmetics to sperm damage, asthma and allergies); *see also* Hatcher, *supra* note 7, at 3-7 (listing substances on SVHC list and uses); *see also* Euractiv.com, http://www.euractiv.com/en/health/permanent-phthalates-ban-toys-approved/article-142028 (last visited Mar. 7, 2009) (discussing European ban of phthalates in 2005).

substantially harm the environment and human health.[189] The article manufacturer, if producing an article (e.g., a toy) with phthalates, therefore faces the choice of altering the component of the article or losing the European market.[190] The costs of this dilemma to the international community are substantial and increase with multiple suppliers; centers of toy manufacturing, such as Hong Kong, will strongly feel the resulting sting of REACH on their products.[191] There are much safer alternatives, however, coming onto the market with each passing day, which can offset the costs, as the demand for organic products increases.[192] Similar—if not more complex—situations face the automotive industries in countries such as Japan and the United States.[193] Finally, while manufacturers say that phthalates do not cause any health problems, simply linking the word "concern" with such a substance is enough to trigger a market reaction, let alone placing the substance on the list of banned chemicals.[194]

3. Catalyst of Element #3: Downstream Users, Energy & Cosmetics

The energy and cosmetic industries also face enormous challenges under REACH.[195] REACH's net catches these two industries because, being based in chemicals, they are considered manufacturers, article producers or downstream users, and therefore they each face similar challenges; the categorization of each is different, however, because the designation is determined by a particular com-

189. *See* Layton, *supra* note 22, at A1 (discussing stigma of chemicals whose effects concern society).

190. *See* Wyness, *supra* note 176 (noting dilemma facing toy manufacturers).

191. *See id.* (discussing impact on business costs of toy industry); *see also* Hong Kong Trade Development Council, Business Alert, Issue 04 (Mar. 3, 2005), *available at* http://info.hktdc.com/alert/eu0504b.htm (discussing impact of REACH on Hong Kong toy industry).

192. *See* Goodman, *supra* note 116 (noting availability of organic alternatives to chemicals used by toy industry).

193. *See id.* (noting automotive industry as article manufacturer faces similar problems as toy industry). For a further discussion of the Japanese automobile industry's compliance with REACH, see *The Views and Policies on Japan's Automobile Industry*, http://eujapan-live.ashleyassociates.co.jp/data/current/dataobj-283-datafile.pdf (last visited Oct. 1, 2009) (discussing REACH implications on Japanese automobile industry).

194. *See* Waldman, *supra* note 139, at A1 (indicating criticism of phthalate ban); *see also* Layton, *supra* note 22, at A1 (discussing potential market reactions of SVHC list).

195. *See* Penman & Bognolo, *supra* note 41 (discussing impact of REACH on cosmetic industry).

pany's role.[196] While not stringently regulated in the United States, the American cosmetic industry in Europe, under REACH, may face especially severe restrictions on substances found in their products, which are commonly found on the United States' market.[197] For example, the European Union may ban certain companies' personal care product lines; components of certain brands of nail polish, shampoo or eye-shadow may no longer be allowed in Europe, despite being on the market in the United States.[198]

V. THE STATE OF THE WORLD'S LABORATORIES: CONCLUSION

REACH compliance will be costly; the European Union has anticipated that companies will spend between two and ten billion dollars just to register substances to achieve full compliance by 2018.[199] While American companies have been preparing for the implementation of REACH, the United States government has been fighting the regulation and objecting vigorously to its potential costs since REACH was first envisioned.[200] There is a concern, furthermore, that if the United States goes beyond simply complying with REACH and attempts to enact similar legislation domestically, it will suffer economic lethargy similar to that endured by Europe.[201] The possibility of future chemical regulation experiments in the United States, however, is growing.[202]

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196. *See* The European Cosmetics Association, http://www.colipa.eu/the-impact-of-reach-on-cosmetic-manufacturers.html?sid=48&smid=126 (last visited Mar. 8, 2009) (discussing different roles within cosmetic industry).

197. *See* Goodman, *supra* note 116 (noting impact of REACH on American cosmetic and toy industries).

198. *See id.* (discussing differences in regulation of personal care products in United States and Europe).

199. *See* ENV'T DIRECTORATE GEN., *supra* note 36, at 9 (graphing timetable for REACH registration); *see also* Rivlin et al., *supra* note 8 (discussing costs of implementing REACH).

200. *See* Layton, *supra* note 22, at A1 (noting Bush Administration's and chemical industry's fight against REACH). In 2002, Secretary of State Colin Powell directed all staffs of the American Embassies in Europe to oppose REACH. *Id.*; *see also* David Brownfield, Comment, *Reform of U.S. Chemicals Regulations May Not Be Out of REACH*, 21 PAC. MCGEORGE GLOB. BUS. & DEV. L.J. 223, 234 (2008) (discussing Bush Administration's fight against REACH).

201. *See* Kogan, *supra* note 159, at 503-04 (concluding United States should not restructure economic and legal system to match Europe). The author foresees stagnant slow-growth regional economies, reduced investments in high-tech research and development, and an outflow of jobs to more "market friendly" jurisdictions. *Id.*

202. For a further discussion of proposed legislation in the United States resembling or inspired by REAC, see *supra* notes 151-55 and accompanying text (discussing stricter chemical regulation being mooted by Obama Administration and proposed in Congress).

With the new Administration in 2009, the United States' position on overhauling its chemical regulation has become more proactive; the House Subcommittee on Commerce, Trade, and Consumer Protection, for example, held a hearing on "Revisiting the Toxic Substances Control Act of 1976" to address gaps in the TSCA.[203] The purpose of the meeting was to jump start discussions on revising a statute that has not seen major revision since the diesel engine was in vogue.[204] To many, proof that the TSCA as enacted has outlived its usefulness is contained in the fact that it does not prohibit asbestos.[205] Reform of the chemical policies and regulation of the United States would not only just be good for human health and the environment, but also for business.[206]

The United States has not repaired its laboratory or conducted an experiment to revise its federal industrial chemical regulation in over thirty years.[207] Its chemical regulation policy could face aggressive challenges and strict reform proposals during the new Administration.[208] GAO, in fact, recently included the EPA's assessment of chemicals on a list of "some two dozen government programs at high risk for waste, fraud, abuse, and mismanagement."[209] During the first several months of the Obama Administration, however, the only attempt to reform chemical regulation in

203. *See generally* Committee on Energy and Commerce, *Revisiting the Toxic Substances Control Act of 1976*, http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1505&Itemid=95 (last visited Mar. 2, 2009) (discussing purpose of subcommittee meeting).

204. *See* Representative Bobby L. Rush, Opening Statement, Committee on Energy and Commerce, Subcommittee on Commerce, Trade and Consumer Protection, Hearing: Revisiting the Toxic Substances Control Act of 1976, Feb. 26, 2009, *available at* http://energycommerce.house.gov/Press_111/20090226/rush open.pdf (discussing purpose of hearing). In his opening statements, Chairman Rush noted that the TSCA is in serious need of reform and, while it is a very ambitious statute, it is very broad and "subject to constant legal action by companies that don't want to comply." *Id.*

205. *See id.* (discussing TSCA components). Chairman Rush notes that many Americans would be "very surprised" to know that asbestos is not prohibited under the TSCA. *Id.*

206. *See id.* (noting positive impact of reforming chemical regulation).

207. *See* Ditz, *supra* note 104, at 1 (introducing status of United States chemical regulation).

208. *See* Cheryl Hogue, *GAO Tags FDA, EPA Program for Reform*, CHEM. & ENG'G NEWS, Jan. 23, 2009, *available at* http://pubs.acs.org/cen/news/87/i04/8704notw10.html (noting regulations in need of reform). Acting Comptroller General Gene Dodaro notes that adding the chemical policies of the United States, including the TCSA, to the list of new high-risk areas of government regulation, will spur reform. *Id.* They are added along with the Financial Regulatory system, which is not necessarily a place where an agency wants to be at the moment. *Id.*

209. United States Government Accountability Office, Report to the Congress, *High Risk Series: An Update*, GAO-09-271 (Jan. 2009) (describing new policies added to high risk areas of regulation).

the United States quietly died in committee.[210] Though the chemical industry "[has] remain[ed] satisfied with the [TSCA] as it stands," and only recently has public concern prompted the United States to reassess its approach to chemical regulation, there has been a growing movement arguing for a shift toward employing the method that Europe uses to regulate chemicals.[211]

Despite their reluctance to embrace REACH with open arms, the United States' chemical industry and government, while complaining of the cost of REACH implementation, should note that, "because European countries pay a far larger share of their citizens' health-care costs than does the U.S., they want to keep [those] costs down."[212] Contrary to one scholar's perception that it is neglecting resulting economic and opportunity costs in search of an "environment-centric, risk-free utopian world,"[213] Europe anticipates that, despite short-term implementation costs, it will save more than fifty billion dollars over the long term from improved health and environmental conditions.[214] The United States should look to its regulatory competition and prepare future experiments to reap the environmental, human health and economic benefits being delivered to Europe.

*Conrad Benedetto**

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210. *See* Newsroom Press Releases, Office of Senator Frank Lautenberg, *supra* note 154 (noting failed bill proposal). Senator Frank Lautenberg introduced the Kids Safe Chemicals Act (KSCA) on May 20, 2008, which failed in committee. *Id.* Sen. Lautenberg, newly Chairman of the Senate Environment and Public Works Committee (EPW) subcommittee, will propose the KSCA again, along with numerous other chemical regulation reform. *See* Press Release, Office of Senator Frank Lautenberg (Feb. 12, 2009) http://lautenberg.senate.gov/newsroom/record.cfm?id=308177 (announcing plans for future environmental regulation, including reintroduction of KSCA).

211. *See* Ditz, *supra* note 105, at 1, 2 (assessing current chemical regulation situation in United States).

212. *See* Goodman, *supra* note 116 (discussing cost of REACH to Europe).

213. Kogan, *supra* note 159, at 495 (dismissing Europe's goals of stricter chemical regulation).

214. *See* Goodman, *supra* note 116 (discussing cost savings in coming decades of chemical regulation); *see also* Simon Pickvance et al., Final Report, *The Impact of REACH on Occupational Health*, at 7 (2005), *available at* http://www.etuc.org/IMG/pdf/REACH-Sheffield-3-2.pdf (noting predicted cost savings of REACH). The study's midpoint estimate of cost savings in health care over a ten-year period is € 3.5 billion. Pickvance et al., *supra* note 214, at 7. The anticipated cost savings over a thirty-year period is over € 90 billion. *Id.*

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